UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.) No. 4:12-WI-32-RWS
)
RICHARD J. TAYLOR,)
)
Defendant.)

4:13CR00297 RWS

INFORMATION

At all times relevant to this Information:

Background

1. Defendant is a resident and citizen of the United Kingdom. He was the owner and operator of Richard's Pharma Limited. Under defendant's supervision and control, Richard's Pharma Limited operated a wholesale facility located in Warwick, England, within the United Kingdom.

The U.S. Food and Drug Administration

2. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce, including the wholesale distribution of prescription drugs.

Prescription Drugs

3. Under the FDCA, drugs included: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, articles intended to affect the structure or any function of the body of man, and "biological products" that met the FDCA's definition of a "drug." 21 U.S.C. § 321(g)(1)(B) and (c); 42 U.S.C. § 262(I) and (j).

4. Under the FDCA a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

5. The drugs listed below, described by their U.S. trade names under which they are marketed in the United States, are used primarily to treat individuals with cancer, and are administered and "infused" to cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients. All of these drugs were "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs:

Neupogen®
Herceptin®
Rituxan®
Gemzar®
Taxotere®
Eloxatin®
Zometa®

Venofer®
Avastin®

Adulteration

6. Under the FDCA, a drug is "adulterated" if the methods used in, or the facilities or controls used for its manufacturing, processing, packing, and holding do not conform to or are not operated or administered in conformity with current good manufacturing practices ("cGMP") to assure that the drug meets the safety requirements of federal law, and has the identity, strength, quality, and purity characteristics which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

Defendant's Wholesale Drug Distribution to the United States

7. From defendant's facility in the United Kingdom, from on or about January 1, 2008 through on or about May 18, 2011, defendant and others distributed and caused the distribution of prescription drugs from foreign countries to physicians located in the United States, with the assistance of persons in California, Canada, and the United Kingdom. The prescription drugs distributed by defendant and others were "new drugs" under 21 U.S.C. § 321(p) that required approval by the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355 before they could be imported into the U.S. Those foreign prescription drugs, however, were not versions that the FDA had approved for use in the United States because, among other things, the drugs' labeling did not conform to the FDA-approved labeling for the U.S. versions. For example, the drugs' labeling for the foreign versions failed to contain the National Drug Code numbers, which are part of the FDA-approved labeling for the U.S.

versions. Moreover, some of the distributed drugs contained non-English language labeling, including use and dosage instructions in the Turkish language.

8. During Fall 2010, defendant, through his business Richard's Pharma Limited. and others began distributing "cold chain" drugs, namely prescription drugs that require a uniform cold temperature during shipment. Generally, the profit margins for "cold chain" drugs were higher for defendant and others than the profit margins for non-cold chain prescription drugs. For example, Neupogen®, Rituxan®, Herceptin®, and Avastin® (sometimes marketed in Turkey as Altuzan) are prescription drugs that are typically intravenously infused into cancer patients. Generally, the U.S. labeling for these drugs require storage of the drugs in a refrigerator at constant temperatures of 2° to 8°C (36° to 46°F), and cautions that the drugs should not be shaken or frozen. According to the U.S. labeling for Neupogen®, if it is left at room temperature for longer than 24 hours, it should be discarded and not used with patients.

9. In Fall 2010, defendant and others began shipping Neupogen® and other "cold chain" drugs, along with other cancer treatment prescription drugs, to Dr. Nisar, who operated an office practice located in Florissant, Missouri, within the Eastern Division of the Eastern District of Missouri, and other physicians in the United States.

10. During September and October of 2010, defendant learned that multiple doctors in the United States had received shipments of "cold chain" prescription drugs that were warm upon arrival and damaged during shipment. Defendant and others discussed and authorized credits to these physicians, recognizing these "cold chain" prescription drugs should not be used on patients when there was a lack of temperature control during shipment of these drugs. Defendant and others discussed placing a thermometer inside drug packages that would be sent to U.S.

customers so that the temperature would be recorded and shown to the U.S. physicians when the drugs arrived at their respective offices was considered. However, the "thermometer in a box" concept was rejected because defendant's associate concluded that "we mutually think adding a thermometer will be opening Pandoras Box if the temp dips and the thermometer shows that we will for certainly be eating a whole bunch of product - for discussion."

The Charge

11. The United States incorporates by reference paragraphs 1-10.

12. On or about October 13, 2010, within the Eastern Division of the Eastern District of Missouri, and the Southern Districts of Illinois and California, and elsewhere, defendant

RICHARD JEFFREY TAYLOR,

with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce quantities of prescription drugs from the United Kingdom to the Eastern District of Missouri and the Southern District of Illinois, specifically the prescription drug marketed in the United States as Rituxan® in two 100 milligram containers, that were adulterated. Specifically, each quantity of the drug was adulterated because the methods of drug holding and shipment were not appropriate and did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug products, including maintaining temperature protection of these prescription drugs. All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B) and 18 U.S.C. § 2.

UNITED STATES OF AMERICA)
EASTERN DIVISION)
EASTERN DISTRICT OF MISSOURI)

I, Andrew J. Lay, Assistant United States Attorney for the Eastern District of Missouri, being duly sworn, do say that the foregoing information is true as I verily believe.

Andrew J. Lay, #28542

Subscribed and sworn to before me this 21 day of November 2012.

CLERK, U.S. DISTRICT COURT

By: DEPUTY CLERK